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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,077	06/23/2003	Stephen Suffin	10701-006-999	1225

23535 7590 09/19/2008

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,077	SUFFIN, STEPHEN	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/8/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-42 and 50-60* is/are pending in the application.

4a) Of the above claim(s) *57-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-42 and 50-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 7/8/08 wherein claims 1-39 and 43-49 were canceled and claims 40 and 54 were amended. In addition, the Examiner acknowledges receipt of the request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/08 has been entered.

Note: Claims 40-42 and 50-60 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 7/8/08 to the rejection of claims 40-42 and 50-56 made by the Examiner under 35 USC 102 and/or 112 have been fully considered and deemed persuasive for reasons of record. Therefore, all outstanding rejections are hereby withdrawn.

NEW GROUNDS OF REJECTION

103 Rejection

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 40-42 and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over John (US Patent No. 6,067,467).

John discloses electrocephalograph (EEG) methods used to monitor patients before, during, and after medical operations (see entire document, especially, abstract). In the background of John, it is disclosed that the EEG system obtains artifact free data samples and that a selected group of features are extracted, normalized, and Z transformed to obtain Quantified EEG (QEEG). Using a database based on experience with a group of normal patients, the patient's discriminant score for probability of a certain characteristic is calculated. In addition, John discloses that the discriminant function utilizes information from the electrodes, frequency bands, and multivariate combinations of variables which are most meaningful to determine changes in a patients state (column 3, lines 53-67). A patient is prepared prior to a surgical operation. A series of EEG electrodes are secured to the scalp of the patient. Possible locations of the electrodes include the from left, front right, center left, center right, back left, and back right of the scalp (column 4, lines 22-28). Initial EEG measurement may be taken while the patient is awake and before the anesthesia is administered (*note that*

the anesthesia is the drug that is being administered) (column 4, lines 42-44). The Anesthesiologist then administers the selected anesthetics to cause the patient to attain the selected plane of anesthesia (column 4, lines 45-48). The EEG system analyzes the data and obtains mean values and standard deviations for absolute and relative power in the delta, theta, alpha, and beta frequency ranges. Specifically, the frequency data is obtained from the Delta 1 (0.5 – 1.5 Hz), Delta 2 (1.5 – 3.5 Hz), Theta (3.5 – 7.5 Hz), Alpha 1 (7.5 – 10 Hz), Alpha 2 (10 – 12.5 Hz), Beta 1 (12.5 - 25 Hz), and Beta 2 (25 – 50 Hz) (column 4, lines 61-67). At regular intervals after the baseline is established, a statically EEG and EP (evoked potential) sample is obtained and compared to the baseline (column 5, lines 7-22). According to Figure 6B, normalization of the data is generated using Gaussian normalization in order that Z-scores may be calculated. Preferred data is obtain for each electrode as it relates to the bands of absolute power, bands of relative power, and coherence of the total EEG and each frequency band. An overall multivariate measurement of deviation is computed for each lead and across selected combinations of leads (columns 7-8, bridging paragraph; column 8, lines 4-12). Various data is compared against the baseline (data collected from the pre-operative patient). Each data point may be Z-transformed using the corresponding mean and standard deviation obtained from the baseline. Each Z-score for a patient is calculated (column 9, lines 19-34). Classification of a patient may be determined using discriminant functions derived from stepwise discriminant analysis of the same patient prior to the operation and/or normal test populations (column 11, lines 16-62). The system of John compares a first set of data form the patient before

anesthesia is administered and a second set of data after the plane of anesthesia is attained, but before the operation. In addition, the system disclosed by John, compares the first set of data from the patient, obtained after the plane of anesthesia is attained with a second set of data obtained during the operation (column 13, lines 1-14). The system monitors drug efficacy because it detects if there is a low mean total EEG power, if there is too little anesthesia, and if there is too much anesthesia (column 13, lines 50-64). The information from the EEG may be combined with other data (i.e., data from an EKG) to provide a multivariate overall state measurement (column 15, lines 20-32).

Thus, since both Applicant and John disclose methods of determining medication efficacy wherein (1) an EEG is taken prior to and during the administration of a medication; (2) obtaining data from the first and second EEGs containing a plurality of Z-scores wherein the data is derived form the delta, theta, alpha, and beta frequency bands; and (3) comparing the data obtained to determine the medication efficacy, the inventions contain overlapping subject matter.

Note: According to any standard medical dictionary (e.g., Dox et al, The Harper Collins Illustrated Medical Dictionary, 1993, page 264), the term 'medication' is defined as a medicine or drug.

WITHDRAWN CLAIMS

6. Claims 57-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

COMMENTS/NOTES

7. Review of Applicant's parent applications indicate that the instant invention was first disclosed in detail (as in the instant claims) in Serial Number 09/501,149 filed February 9, 2000. Thus, this is Applicant's priority date for the pending claims. If Applicant is in disagreement with the Examiner, it is respectfully requested that Applicant point to page and line number(s) and specify the parent application wherein support for the pending claims is found.

8. Applicant is respectfully requested to cancel the non-elected subject matter (claims 57-60).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

September 12, 2008